DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 13, 2014

3M Health Care
Dr. Suzanne Leung, Ph.D., RAC
Regulatory Affairs Manager
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144

Re: K140392
Trade/Device Name: 3M Attest™ Rapid Readout Biological Indicator 1295 and 3M Attest™ Auto- reader 490H
Regulation Number: 21 CFR 880.2800(a)
Regulation Name: Biological sterilization process Indicator
Regulatory Class: II
Product Code: FRC
Dated: July 14, 2014
Received: July 17, 2014

Dear Dr. Leung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140392

Device Name
3M Attest™ Rapid Readout Biological Indicator 1295 and 3M Attest™ Auto-reader 490H

Indications for Use *(Describe)*
Use the 3M Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M Attest™ Auto-reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in STERRAD® NX and 100NX systems.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification (510(k)) Summary

K140392

Sponsor Information:

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Regulatory Affairs Manager

Phone Number: (651) 575-8052
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Date of Summary: August 11, 2014

Device Name and Classification:

Common or Usual Name: Sterilization Biological Indicator

Proprietary Name: 3M Attest™ Rapid Readout Biological Indicator 1295
3M Attest™ Auto-reader 490H

Classification Name: Indicator, Biological Sterilization Process
(21 CFR § 880.2800(a))

Product Code: FRC
Product Class: Class II

Predicate Devices:

New Device	Predicate
Attest™ 1295 Rapid Readout BI	'Intended Use Predicate' – shares same Intended Use as STERRAD® CycleSure® 24 BI, K123017
	'Design Predicate' – shares same BI design as Attest™ 1492V Super Rapid Readout BI, K121484
3M Attest™ Auto-reader 490H	3M Attest™ Auto-reader 490, K121484

Description of Device:

Attest™1295 BI

The 3M Attest™ 1295 Rapid Readout Biological Indicator for Vaporized Hydrogen Peroxide Sterilization (pink cap, referred to hereinafter as the 1295 BI) is a self-contained biological indicator specifically designed for rapid and reliable routine monitoring of STERRAD® vaporized hydrogen peroxide sterilization processes when used in conjunction with the 3M Attest™ Auto-reader 490H (hereinafter referred to as the 490H Auto-reader). The 1295 BI is a single-use device.

The Attest™ 1295 BI is composed of a polycarbonate sleeve containing a spore carrier and media ampoule, enclosed with a color-coded cap. A chemical process indicator printed with stripes which change from blue to pink upon exposure to vaporized hydrogen peroxide is located on the top of the cap.

The 1295 BI utilizes the same fundamental technology that exists in current 3M Attest™ Rapid Readout and Super Rapid Readout BIs. All Attest™ Rapid Readout and Super Rapid Readout BIs for steam utilize the α-glucosidase enzyme system, which is generated naturally within growing *Geobacillus stearothermophilus* organisms. The α-glucosidase enzyme in its active state is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected in the 3M Attest™ 490H Auto-reader. The detection of fluorescence upon incubation of the 1295 BI in the 490H Auto-reader indicates a sterilization failure.

The 1295 BI is similar in design to the 3M Attest™ 1492V Super Rapid Readout Biological Indicator for Steam cleared as K121484 for dynamic-air-removal (prevacuum) steam sterilization cycles. Minor modifications were made to 1492V that resulted in the 1295 BI for STERRAD® vaporized hydrogen peroxide sterilization cycles.

Attest™ Auto-reader 490H

The Attest™ Auto-reader 490H is similar in design to the Attest™ Auto-reader 490 that has been cleared for use with the Attest™ 1491 Super Rapid Readout Biological Indicator under K103277 and Attest™ 1492V Super Rapid Readout Biological Indicator under K121484.

The Attest™ Auto-reader 490H is designed to incubate at 60^{o}C and automatically read the Attest™ 1295 BI for a fluorescent result within 4 hours. The fluorescent readout at 4 hours met the FDA's requirement of > 97% alignment with the result after the conventional incubation time of 7 days. The Auto-reader 490H is also designed to allow further incubation of the 1295 BI for an optional visual pH color change result of the growth media at 7 days.

Indications for Use:

Use the 3M Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M Attest™ Auto-reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in STERRAD® NX and 100NX systems.

Substantial Equivalence of Attest™ 1295 Rapid Readout BI to 'Intended Use' Predicate Device STERRAD® CycleSure® 24 BI:

The Attest™ 1295 Rapid Readout BI has the same Intended Use as the predicate device, the STERRAD® CycleSure® 24 BI, cleared under K123017. Both the 1295 Rapid Readout BI and the predicate are biological indicators that are intended to be used in healthcare facilities to monitor the adequacy of hydrogen peroxide sterilization processes. This is accomplished through the biological challenge of *Geobacillus stearothermophilus* spores. Growth of the spores within the biological indicator after processing, indicates a failure of the hydrogen peroxide sterilization process.

Testing was conducted on the Attest™ 1295 BI following the FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions; October 4, 2007.* Multiple lots of Attest™ 1295 BIs were evaluated for performance when used with the Attest™ 490H Auto-reader.

A test cycle was developed for resistance testing utilizing a 10 mg/L hydrogen peroxide concentration, which is much more challenging than that used for evaluation of the predicate device. Despite using a higher hydrogen peroxide concentration, the Kill time for the Attest™ 1295 BI at 7 minutes is still much longer than the CycleSure® BI, reflecting its higher resistance. The greater resistance of the 1295 BI imparts a superior challenge to the sterilization process and provides a larger margin of sterility assurance.

An additional benefit of the Attest™ 1295 BI is the faster time to result. Through the use of the Attest™ Rapid Readout technology, the Reduced Incubation Time, performed according to FDA's guidance for biological indicators, has been validated at 4 hours. The more rapid time to result for the Attest™ 1295 BI over the CycleSure® BI allows for increased patient safety as the faster answer will reduce the number of patients affected should there be a sterilization failure.

The results of these evaluations showed that the new Attest™ 1295 Biological Indicator, when used with the Attest™ 490H Auto-reader, complies with the FDA's Guidance for Biological Indicators and is substantially equivalent to the predicate device, the STERRAD® CycleSure® 24 BI for the intended use with STERRAD® NX and 100NX cycles.

A summary of the testing and predicate comparison is provided below.

DEVICE CHARACTERISTIC	**'INTENDED USE PREDICATE'** STERRAD® CycleSure® BI K123017	**NEW DEVICE** Attest™ 1295 BI
Intended Use • Method of sterilization	Vaporized hydrogen peroxide	Same as predicate
Indications for Use	The STERRAD® CycleSure® 24 BI is intended to be used as a standard method for frequent monitoring of the following STERRAD® Sterilization Systems: • STERRAD 100S • STERRAD 50 • STERRAD 200 • STERRAD NX • STERRAD 100NX • For STERRAD 100NX DUO Cycle in the United States, the STERRAD CYCLESURE 24 Biological Indicator should only be used in a test pack configuration.	Use the 3M Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M Attest™ Auto-reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in STERRAD® NX and 100NX systems.
Organism • Spore, Species, Strain	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	Same as predicate
Viable Spore Population	$\geq 10^6$	Same as predicate
Carrier Material	Glass Fiber	PET (Polyethylene terephthalate)
Resistance Characteristics: • D-value • Survival/Kill Window	**Tested at 2.5 mg/L vaporized hydrogen peroxide** $D_{2.5\ mg/L} \geq 1$ second Survival Time ≥ 5 seconds Kill Time = 60 seconds	**Tested at 10 mg/L vaporized hydrogen peroxide** $D_{10\ mg/L} \geq 1$ second Survival Time ≥ 5 seconds Kill Time = 7 minutes
Incubation Temperature	55-60°C	60 +/- 2 °C
Reduced Incubation Time (>97% correlation to the 7-day visual pH color change result)	Visual pH color change result in 24 hours	Fluorescent result in 4 hours
Chemical Process Indicator	Turns from red to golden yellow or bronze	Chemical indicator on the BI cap changes from blue to pink
Shelf-life	6 months	6 months, will be extended with available real time aging data

Substantial Equivalence of Attest™ Auto-reader 490H with Auto-reader 490:

Both the new Auto-reader 490H and the predicate Auto-reader 490 share the same Intended Use. These devices incubate and read Attest™ Rapid Readout biological indicators to determine a positive or negative result based on a fluorescence signal. The difference between the devices is in their Indications for Use. The Auto-reader 490H is intended for use with the Attest™ 1295 BI for hydrogen peroxide while the predicate Attest™ Auto-reader 490 is intended for use with the Attest™ Super Rapid Readout 1491 and 1492V Biological Indicators for steam. The difference in biological indicators being incubated leads to a difference of target incubation temperatures and time to result between the 490H and the 490.

The Attest™ Auto-reader 490H was tested for safety by Underwriters Laboratory to verify compliance to applicable electrical safety standards including *IEC 61010-1 (2001) Second Edition* and *IEC 61010-2-010 (2003) Second Edition.* In addition, the Attest™ Auto-reader 490H has been tested by a certified Testing Laboratory to verify electromagnetic compatibility per USA Title 47, Code of Federal Regulations (2009) for Radiated Emissions (FCC Part 15, Subpart B, Class A) and Conducted Emissions (FCC Part 15, Subpart B, Class A).

Device Function or Characteristic	**PREDICATE 3M Attest™ 490 Auto-Reader K121484**	**NEW DEVICE 3M Attest™ 490H Auto-Reader**
Statement of Intended Use	The 3M Attest™ 490 Auto-reader is designed to incubate and automatically read the 3M Attest™ Super Rapid Readout Biological Indicators at 56°C for a final fluorescent result at 30 minutes for 1491 and 1 hour for 1492V.	The 3M Attest™ 490H Auto-reader is designed to incubate and automatically read the 3M Attest™ 1295 Rapid Readout Biological Indicator at 60°C for a final fluorescent result at 4 hour.
Incubation Temperature	56°C ± 2°C	60°C ± 2°C
Basis of Rapid Readout	Fluorescence of biological indicator medium	Same
Use with Biological Indicators	3M Attest™ Super Rapid Readout Biological Indicators 1492V, 1491	3M Attest™ Rapid Readout Biological Indicator 1295
Color-coded configuration indicator (racetrack around incubation wells)	Blue (1491 BI), Brown (1492V BI), or Blue and Brown (both 1491 and 1492V)	Pink (1295 BI)
Method of Fluorescence Detection	UV LED, optical filters, with sensing by photo diode	Same
Indicator of Adequate Sterilization Cycle	(-) on LCD Display	Same
Indicators of Possible Sterilization Cycle Failure	(+) on LCD Display Audible Alarm	Same
Incubation Wells	10 – reader/incubation wells	Same
Voltage Range	100-240 Volts AC (12 Volt DC conversion for internal circuitry)	Same
Product Safety	UL/IEC 61010-1	Same
EMC Compliance	FCC Part 15, Subpart B, Class A	Same

Conclusion

The 3M Attest™ 1295 Rapid Readout Biological Indicator and the 3M Attest™ Auto-reader 490H meet all applicable performance standards and are substantially equivalent to their predicate devices in terms of their intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.